MISSOURI BOARD OF PHARMACY
NEWSLETTER

MAY 2016

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CONGRATULATIONS TAMMY!

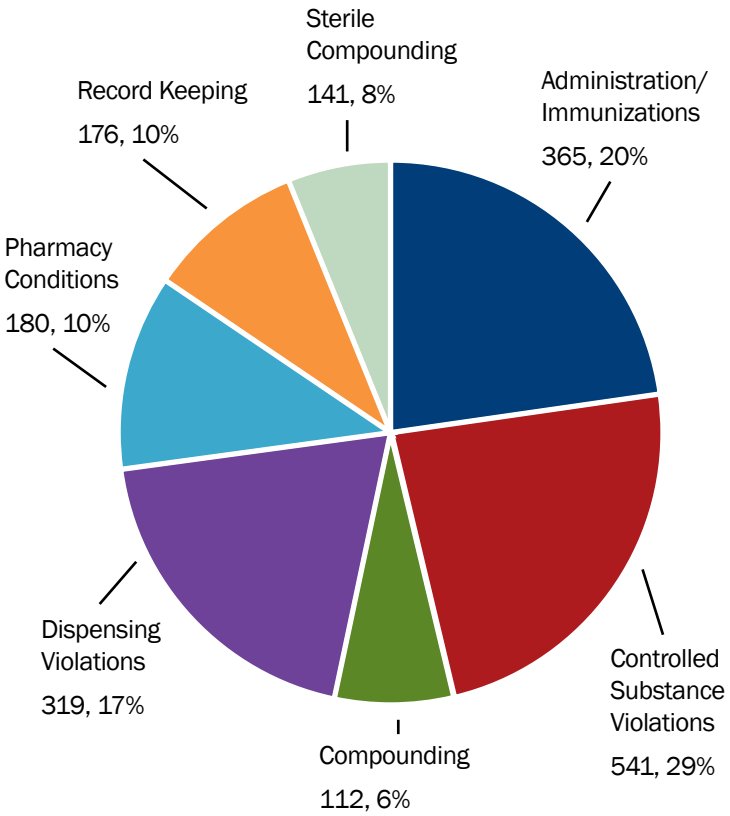
Congratulations to Tammy Siebert who recently retired after 23 years with the Missouri Board of Pharmacy. Tammy finished her career with the Board as the Administrative Coordinator where she helped to supervise and direct all of the Board's administrative and licensing functions. Best wishes Tammy and thanks for your excellent service to the Board and Missouri's citizens!

FY 2015 INSPECTION SUMMARY*

The Board office is frequently asked about the most common inspection/compliance violations. A summary of inspection violations observed by inspectors in FY 2015 is provided below. "Compliance starts before an inspection. The FY 2015 inspection summary gives the Board a chance to review what the inspectors are seeing in the field and helps them identify where we may need to provide more education," Board President Christina Lindsay said. "Licensees should use the inspection summary as a tool to make sure your pharmacy is in compliance before an inspector visits."

Board inspectors cited a total of 1,839 pharmacy compliance violations during FY 2015 in the following categories:

(Category, # of violations cited and percentage of total violations)



*** Based on available Board data.*

FY 2015 TOP VIOLATIONS BY CATEGORY

The top three violations in each category are listed on the next page along with compliance tips.

Administration/Immunization Violations

1. Immunization Notifications (missing, late, incomplete) (36%)	Pharmacists are required to notify their authorizing physician within 72 hours after immunizing and notify the patient's primary care physician within 14 days, if different than the authorizing physician. Pharmacists should review 20 CSR 2220-6.050(7) to make sure notifications include all required information. Notification is the pharmacist's responsibility.
2. Immunization protocol violations (19%)	Violations involved incomplete, unsigned or missing protocols. Check your protocol to make sure it complies with 20 CSR 2220-6.050(5). Also make sure the protocol has also been signed and dated by both the pharmacist and protocol physician.
3. Administration prescription incomplete (10%)	Most of the violations involved prescriptions to administer a drug that did not have the required prescription statement. 20 CSR 2220-6.040(5) requires that prescriptions for pharmacist drug administration must specifically state that "the drug is to be administered by a pharmacist" on the prescription.

Controlled Substance Violations

1. Inventory Violations (39%)	Multiple pharmacies took their controlled substance inventories late and not annually as required. Additionally, several pharmacies failed to take an inventory of hydrocodone when it was rescheduled in 2015. 21 CFR § 1304.11(d) requires that an inventory must be taken whenever a substance is added to any schedule. The other major violation in this category involved pharmacies that failed to note if the controlled substance inventory was taken at the opening or close of business, in violation of 19 CSR 30-1.042 and 21 CFR § 1301.11. This information must be noted on each inventory.
2. Prescription violations (incomplete, unsigned, not authorized, electronic Rx converted to fax) [18%]	Inspectors observed multiple electronic controlled substance prescriptions that were converted to faxed prescriptions. According to the DEA, what starts electronic must stay electronic. An electronic prescription cannot be converted to another form (e.g., a fax) and dispensed. 21 CFR § 1311.170(f).
3. Improper Security (12%)	The majority of violations involved unlocked CII cabinets or CII cabinets with keys left unattended in the lock. Controlled substance registrants must provide effective controls and procedures to guard against theft and diversion. CII cabinets should be locked and keys properly secured.

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General Compounding Violations **

1. Compounding log inaccurate/ incomplete (35%)	Compounding log requirements are listed in 20 CSR 2220-2.400(7). Pharmacists should review the log before signing it to make sure the log is accurate and complete. Be sure to look at ingredient expiration dates to make sure no expired products were used.
2. Beyond-use-date (BUD) greater than ingredients (29%)	Pharmacists should consider the ingredients' expiration date prior to assigning a BUD. This violation could threaten patient health and may also constitute misbranding/adulteration under state and federal law.
3. Compounding commercially available products (14%)	20 CSR 2220-2.400(9) specifically prohibits compounding of a commercially available product. Variations of a commercially available product are allowed if there is a specific medical need that is documented in the prescription record.

*** Sterile v. non-sterile not differentiated in report*

Dispensing Violations

1. Dispensing Errors (32%)	Licensees are responsible for making sure medication is properly dispensed. Visit ISMP's website for tips on preventing medication errors.
2. Labeling Errors (16%)	
3. Failure to verify source of fax/ photocopied prescriptions (12.5%)	Pharmacists must verify the source and authenticity of all faxed prescriptions. Pharmacists should consider: • Maintenance of a practitioner's fax number reference or electronic signature file; • Verification of the telephone # where the fax originated from; • Verifying the prescription by phone with the prescriber's office; and • Any other efforts in the pharmacist's professional judgment which may be necessary to verify or ensure the prescription is authentic. [20 CSR 2220-2.085) (2)]

Pharmacy Conditions

1. Improper drug storage (18%)	Violations included drugs stored outside of temperature requirements and/or drugs stored in unsanitary areas (e.g., excessive dust, trash). Check the pharmacy to make sure it is properly cleaned and temperature-controlled drugs are properly refrigerated or frozen.
2. Unsanitary pharmacy conditions (15%)	Once again, inspectors observed pharmacies with excessive dust, trash or other debris. The inspectors noted multiple instances of dirty reconstitubes. Pharmacies should be cleaned regularly, including, pharmacy equipment.
3. Pharmacy permit violations (11%) & Improper Refrigeration/ Temperature controls (11%)	Most of the permit violations involved pharmacies participating in shared pharmacy services without a Class-J Shared Services permit. A Class-J permit is required if you are providing assistance to or receiving assistance from another pharmacy with functions associated with the dispensing process [20 CSR 2220-2.650]. This would include shared services such as filling prescriptions, DUR, claims adjudication or refill authorizations. Both the participating and receiving pharmacy need a Class-J permit. The other violation in this category involved refrigeration/temperature controls that were broken or inaccurate. Check to make sure thermometers and other temperature devices are properly working.

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Record Keeping

1. Polices & Procedures Missing/ Incomplete (65%)	Policies and procedures should be current and include all required information. The Missouri Pharmacist Practice Guide contains a detailed list of required policies and procedures.
2. Prescription records incomplete, inaccurate or missing (23%)	Non-control prescription hard copies must be retrievable at time of inspection or comply with Electronic Record-Keeping System requirements [20 CSR 2220-2.083]. Controlled substance prescriptions shall be maintained as required by state and federal law.
3. Policies & procedures unavailable (4.5%)	Use the Inspector Records Locator Form to write down where policies & procedures can be found during an inspection and share the form with pharmacy staff.

Sterile Compounding

1. Cleaning/ Unsanitary conditions (35%)	Inspectors cited multiple instances of improperly cleaned hoods/ISO classified areas, excessive supplies in the compounding area and unnecessary items on or in the hood. Proper environmental controls and cleaning procedures should be in place to prevent particle generation and environmental contamination.
2. Aseptic technique validation not conducted/ documented annually (15%)	All pharmacy staff who compound sterile products must pass a process validation of aseptic technique before compounding and must be reevaluated at least annually. [20 CSR 2220-2.200(8)] Documentation of the training/competency evaluation must be maintained in the pharmacy for at least two (2) years and available for inspection. ****See the Sterile Compounding Tips****
3. Policies & procedures (incomplete, missing, not annually reviewed) (14%)	Sterile compounding pharmacies must have a policy and procedure manual that encompasses "all aspects" of sterile compounding. [20 CSR 2220-2.200(2)]. Manuals must be reviewed annually and available during an inspection.

PHARMACIST RENEWAL REMINDERS

All Missouri pharmacists must renew their licenses before October 31, 2016. Generally, Missouri pharmacists are required to complete 30 hours (3.0 CEU) of approved continuing education (CE) in order to renew (20 CSR 2220-7.080). For the 2016 renewal, CE must be completed between November 1, 2014 and October 31, 2016, to be eligible. See the pharmacist CE summary from the February 2016 newsletter for additional information.

UPCOMING FREE PHARMACIST CE!

JUNE 08

The Board will be hosting a webinar entitled "Rx: An Ethical Profession?" The webinar will focus on the intersection between compliance and pharmacy ethics. The free webinar will be hosted by Chelsea Church, PharmD, BCPS with the Oklahoma State Board of Pharmacy on June 8th from 12:00 to 1:15. The webinar has been Board approved for 1.15 hours of pharmacist CE. Register now on the Board's website.

2016 CALENDAR

MARK YOUR CALENDAR

THE 2016 "LUNCH WITH THE CHIEF" WEBINAR SERIES

The series will be hosted from 12 p.m. to 1 p.m. on:

AUG	OCT
04	25

Webinar topics will be posted closer to the webinar.

UPCOMING BOARD MEETING DATES

The Board's 2016 in-person meetings will be held on:

JULY	JULY	OCT
19-21	19-20	26-27
	Strategic Planning Date	

All meetings will be held at the Hilton Garden Inn, 3300 Vandiver Drive, Columbia, Missouri. Visit the Board's website for additional meeting information, including, proposed agenda items.

SAVE THE DATE!

The 3rd annual Joint Patient Safety Conference will be held on October 6th in Jefferson City, Missouri. The free conference will provide cutting-edge best practices and tools to improve patient safety. The conference is Board approved for pharmacist continuing education (CE). Registration will open soon.

OCT
06

INSPECTION TIP

All drug distributions from a pharmacy are required to be documented. This includes intra-company transfers, returns for credit/destruction, distributions to other pharmacies or practitioners, and "borrow"/"loan" scenarios. Controlled substance distribution must be in compliance with both state and federal controlled substance regulations. Distributions of schedule II drugs require the use of DEA Form 222 or CSOS equivalent. A hospital distributing to its health system's off-site clinics and other locations should confirm the off-site locations fall under the hospital's license and controlled substance registration.

STERILE COMPOUNDING CORNER

Process Validation of Aseptic Technique (media fills)

Aseptic technique validation **is required by 20 CSR 2220-2.200(8)** and is an important tool for assessing the competency of your sterile compounding personnel. Many pharmacies are deficient in maintaining an appropriate validation program for their employees' aseptic technique.

Here are some tips to help your pharmacy improve their compliance with process validation for aseptic technique:

- Complete media fill tests during initial training and on an annual basis thereafter.
- Maintain appropriate documentation of media fill test results. Include important aspects such as dates, incubation temperatures, length of incubation, presence of growth, pass/fail results etc.
- Ensure that the media fill test simulates a process that is appropriate for your risk level and represents your pharmacy's most challenging compounding activity. If you are using a media fill kit, feel free to change the manufacturer's directions to better reflect your own compounding practices.

- Maintain a copy of your pharmacy's media fill test procedure.
- Utilize media fill testing as a time to observe your employees' aseptic technique and provide feedback! Plus, it will be easier to investigate the cause of a failed media test having observed the employee.

DISCIPLINARY ACTIONS

PHARMACISTS:

Shawn D. Borman, #2002027612, St. Louis, MO. Five (5) years probation. Found guilty, or entered a plea of guilty or nolo contendere to one count of Fraudulently Attempting to Obtain a Controlled Substance, Section 338.055.2(1), (2), (5), (6), (13), (15) and (17), RSMo.

Joseph L. Floyd, #2001018151, Grandview, MO. Revoked, cannot reapply for seven (7) years. Misappropriated controlled substances from employers, incorrectly dispensed controlled and non-controlled substances, dispensed improperly labeled prescriptions, and improper personal use of controlled substances. Section 338.055.2(1), (5), (13), (15) and (17), RSMo.

Amanda A. Radtke, #2009011857, O'Fallon, IL. Revoked, cannot reapply for seven (7) years. Misappropriated controlled substances from employers; created, forged and dispensed prescriptions that were not authorized and were not dispensed to real patients and either removed them for her own possession or provided them to unknown individuals. Section 338.055.2(5), (6), (13), and (15), RSMo.

PHARMACIES:

Target Pharmacy #16845, permit #2015043696, St. Louis, MO. Restricted permit issued on Probation until 2/21/17. Previous owner disciplined for loss of controlled substances and failure to provide adequate security controls to prevent employee theft of controlled substances. Section 338.055.2(5), (6), (13), and (15), RSMo.

Walgreens #05278, permit #2000157695, Kansas City, MO. Three (3) years probation. Loss of controlled substances due to technician diversion and failure to maintain security for controlled substances sufficient to guard against theft and diversion. Section 338.055.2(6) and (15), RSMo.

INSTITUTE FOR SAFE MEDICATION PRACTICES SAFE MEDICATION ALERT

The following article was published by the Institute for Same Medication Practices (ISMP) and is reprinted with permission of ISMP. This article is being provided for informational purposes only and does not express or represent the views or opinions of the Missouri Board of Pharmacy.

CUP WITH WRONG MEASUREMENT MARKING

Figure 1. Cup has 5 mL marking where 10 mL marking belongs.

A 30 mL dosing cup distributed by Essential Medical Supply (model # C1108) has an incorrect marking of 5 mL at the 10 mL gradation. The cup has the correct mL markings for the other gradations, but sequentially, the markings are listed as 2.5 mL, 5 mL, 7.5 mL, and 5 mL (Figure 1). As far as we know, these dosing cups have primarily been distributed to outpatient pharmacies, but please be certain you are not using them. Both the pharmacist at the hospital who reported the error and ISMP have contacted the distributor. We also notified the US Food and Drug Administration (F D A), and the Center for Devices and Radiological Health (CDRH) is investigating the issue. ISMP believes that a recall is in order, but it has not yet occurred. Two-fold dosing errors, which could cause serious harm depending on the drug, are inevitable given the incorrectly marked gradation on the cup.

NATIONAL ASSOCIATION OF BOARDS OF PHARMACY® NATIONAL PHARMACY COMPLIANCE NEWS - 2ND QUARTER 2016

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FDA APPROVES NALOXONE NASAL SPRAY TO PREVENT OPIOID OVERDOSE DEATHS

Food and Drug Administration (FDA) has approved Narcan nasal spray, a life-saving medication that can stop or reverse the effects of an opioid overdose. Prior to this approval, naloxone was only approved in injectable forms, most commonly delivered by syringe or auto-injector, explains FDA in a news release.

Narcan nasal spray does not require assembly and delivers a consistent, measured dose when used as directed. This prescription product can be used on adults or children and is easily administered by anyone, even those without medical training. The drug is sprayed into one nostril while the patient is lying on his or her back, and can be repeated if necessary. However, it is important to note that it is not a substitute for immediate medical care, and the person administering Narcan nasal spray should seek further immediate medical attention on the patient's behalf. The use of Narcan nasal spray in patients who are opioid dependent may result in severe opioid withdrawal characterized by body aches, diarrhea, increased heart rate (tachycardia), fever, runny nose, sneezing, goose bumps (piloerection), sweating, yawning, nausea or vomiting, nervousness, restlessness or irritability, shivering or trembling, abdominal cramps, weakness, and increased blood pressure. Narcan nasal spray is distributed by Adapt Pharma, Inc, of Radnor, PA. The FDA News Release is available at www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm473505.htm.

FDA PROVIDES TRAINING VIDEOS ON MEDWATCH RESOURCES AND BREAKTHROUGH THERAPY

FDA Drug Info Rounds, a series of online videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. In the January 2016 Drug Info Rounds video, "MedWatch Tips and Tools," pharmacists discuss reporting adverse events to FDA's MedWatch program and the resources available for health care professionals to report safety information. In the December 2015 Drug Info Rounds video, "Breakthrough Therapy," pharmacists discuss the breakthrough therapy designation program, which is intended to expedite the development and review of drugs for serious or life-threatening conditions. Drug Info Rounds is developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research, Office of Communications, Division of Drug Information. All Drug Info Rounds videos can be viewed on the FDA website at www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm.

READING MEDICINE LABELS HELPS REDUCE ACETAMINOPHEN OVERDOSES

The Acetaminophen Awareness Coalition (AAC) reminds pharmacists and other health care providers to encourage patients to properly read medicine labels to avoid unintentional acetaminophen overdoses. The coalition also encourages pharmacists and other health care providers to talk to their patients about medicine safety and acetaminophen use. AAC's "Know

Your Dose" campaign reminds patients to take these four steps to avoid acetaminophen overdose:

1. Always read and follow the medicine label.
2. Know if your medicines contain acetaminophen.
3. Take only one medicine at a time that contains acetaminophen.
4. Ask your health care provider if you have questions.

Additionally, pharmacists may download or order free educational materials, including posters, flyers, and talking points, to give their patients on the Know Your Dose website at www.knowyourdose.org.

OVER-THE-COUNTER CHILDREN'S MEDICINE RECALLED DUE TO INCORRECT DOSE MARKINGS

In January 2016, Perrigo Company voluntarily recalled two lots of children's guaifenesin grape liquid cough medicine (100 mg/5 mL) and three lots of children's guaifenesin DM cherry liquid cough medicine (100 mg guaifenesin and 5 mg dextromethorphan HBr/5 mL) sold in 4 oz bottles. The recall

was initiated because some packages contain an oral dosing cup with incorrect dose markings. The affected products were sold by distributors nationwide and distributed through retail stores. The recalled lots and store brands are available in the Perrigo press release posted on the company's website, www.perrigo.com, under "Investors." To date, the company has not received reports of overdose. Distributors and retailers that have the affected lots should stop distribution and return the product using the information provided in the press release.

Adverse reactions or quality problems may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program at www.fda.gov/MedWatch.

FDA OFFERS WEBINARS ON ONLINE DRUG INFORMATION RESOURCES FOR STUDENTS AND CLINICIANS

FDA's Division of Drug Information in the Center for Drug Evaluation and Research presents a series of continuing education webinars targeted toward students and health care providers who wish to learn more about FDA and drug regulation. The webinars are presented by FDA staff and allow participants to interact with staff. Past topics have included "Introduction to FDA's MedWatch Adverse Reporting Program" and "An Overview of the FDA's Breakthrough Therapy Designation Program." Previous webinars and presentation slides can be accessed on FDA's website at www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/PharmacyStudentExperientialProgramCDER/ucm228391.htm.

GLADES DRUGS RECALLS COMPOUNDED VITAMINS DUE TO HIGH VITAMIN D3

On November 25, 2015, Glades Drugs of Pahokee, FL, issued a voluntary recall of compounded multivitamin capsules containing high amounts of vitamin D3 (cholecalciferol), which were distributed nationwide. FDA has received reports of several adverse events potentially associated with these compounded capsules made by Glades Drugs. Consuming this product may result in vitamin D toxicity, which may be severe and may lead to life-threatening outcomes if left untreated, indicates an FDA safety alert. Patients who have received these compounded capsules should stop taking this medication and immediately seek medical attention.

The agency notes further that patients suffering adverse effects from high vitamin D levels may not initially show symptoms. Symptoms of short-term vitamin D toxicity are due to high calcium levels (hypercalcemia) and include confusion, increased urination, increased thirst, loss of appetite, vomiting, and muscle weakness. Acute hypercalcemia may intensify tendencies for heart arrhythmias and seizures, and may increase the effects of certain heart drugs. Long-term toxicity may cause kidney failure, increase in calcium deposits in the blood and soft tissue, bone demineralization, and pain. Patients with conditions such as liver disease or chronic kidney failure may be at increased risk for developing vitamin D toxicity. Health care providers should quarantine and return the recalled products to Glades Drugs, using the information in the safety alert. FDA recommends health care providers report adverse events or side effects to FDA's MedWatch Safety Information and Adverse Event Reporting Program at www.fda.gov/MedWatch. Further details are available in a recall notice posted to the FDA website at www.fda.gov/Drugs/DrugSafety/ucm474552.htm.